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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,608	04/28/2006	Jan Faergemann	G8575.0002	6148

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	PAPER NUMBER
1627	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,608	FAERGEMANN ET AL.	
	Examiner	Art Unit	
	UMAMAHESWARI RAMACHANDRAN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,8-14 and 18-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,8-14 and 18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/9/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election of group I without traverse and election of Staphylococcus as species and Staphylococcus Aureus as the subspecies with traverse is acknowledged. Applicants' arguments regarding the species election have been fully considered and found to be persuasive. Accordingly, the species election is withdrawn. However the group restriction is maintained. Thus the restriction requirement election of Group I claims is made final. According to the restriction requirement and election of Group I by the Applicants' claims 1, 2, 4, 8-14 and 18-25 are pending and will be examined based on the merits.

Application Priority

This application is a 371 of PCT/SE04/01001, 6/23/2004. Applicant's claim priority to foreign application, Sweden 0301862-9, 6/26/2003.

Information Disclosure Statement

The information disclosure statements (IDS) filed on 3/1/2006 and 9/18/2006 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS is being considered by the Examiner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 7, 8, 10, 11, 20, 22, 23, 24, 26 of copending Application No. 11/791,577.

Claims 1 and 18 of the instant application is drawn to a method of inhibiting the growth of bacteria comprising administering pentane-1, 5-diol or a method of disinfecting a non-porous surface contaminated with multiple resistant bacteria comprising administering a disinfecting composition comprising 15% or more by weight of pentane 1,5 diol.

Claims 1, 2, 4, 7, 8, 10, 11, 20, 22, 23, 24, 26 of copending Application No. 11/791,577 are drawn to a pharmaceutical composition comprising 15, 16, 17, 18, 19 or 20 % weight of the diols including 1, 2 pentane diol and use of such composition as antimicrobial composition.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the co-pending application teach the use of a pharmaceutical composition comprising 1, 2 pentane diol in treating microbial infections.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 8-10, 18, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck et al. (U.S. 5,369,129).

Swanbeck et al. teaches a preparation for topical treatment of infections caused by virus, fungi, bacteria comprising 1, 5 pentane diol. The reference teach a composition comprising 50% of 1, 5 pentane diol and 50% ethanol solution (see abstract, col1, lines 56-57). Also, the reference has data showing a study of pentane-1,5 diol against certain bacteria such as S.aureus, S.epidermidis, C.albicans, T.rubrum, P.avale (Table 1). The reference teaches a method of treating an infection caused by a virus by topical administration of a composition comprising 1,5-pentane diol.

The reference does not explicitly teach the topical administration of the composition in patients with bacterial infections.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have topical administered a composition comprising 15% by weight or more of pentane 1,5 diol and a pharmaceutical carrier in a method of treating patients with bacterial infections because the patent title is "Preparation of topical treatment of infections caused by bacteria" and the patent teaches administration of such composition to patients with herpes virus. The reference teaches the preparation of the composition claimed and administration of the same to the patients with viral infections. Also, the reference teaches that formulation is effective against bacteria such as S.aureus, S.epidermidis, C.albicans, T.rubrum, P.avale (Table 1). One having ordinary skill in the art would have been motivated to administer the composition claimed to patients with bacterial infections topically in expectation of success as well to achieve the therapeutic benefits attained in such administration. The reference shows data in study 2 of the activity of pentane 1, 5 diol against various bacteria and an in vitro study of using pentane 1, 5 diol to study its activity against virus. Though the reference does not explicitly teach addition of an antimicrobial composition comprising pentane 1, 5 diol to non-porous surface in a method of disinfecting however it is obvious to one having ordinary skill in the art that addition of such composition to glass surfaces indicates a method of disinfecting the glass surface or non porous surface as pentane 1, 5 diol is taught as an antibacterial agent by Swanbeck. The reference does not explicitly teach rinsing the surface with water or an aqueous detergent composition after treating the

surface with 1, 5 pentane diol. It would have been obvious to one having ordinary skill in the art at the time of the invention to have rinsed surfaces at least with water that has been treated with disinfectants or antimicrobial such as 1, 5 pentane diol in order to clean and remove the antimicrobial composition from the surface.

Claims 1, 8, 10-13, 20, 22, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (U.S. 6,348,203) and further in view of Tsao et al. (5,411,597).

Goodman et al. teaches a method of preparing a viscous hydrogel composition, for use in a topical treatment of a skin condition including a pharmaceutically active agent, a polysaccharide, gelling or a thickening agent (col.2 , lines 12-13) (e.g. hydroxy alkyl cellulose), a water-miscible organic solvent and water, wherein the pharmaceutically active agent is an antimicrobially active nitroimidazole drug (0.75% in example 1), the water-miscible organic solvent is a water-miscible alkylene glycol that includes pentylene glycol (synonym of 1,5 pentylene glycol or 1, 5 pentane diol) (see abstract, col. 5-6, claim 1, claims 22, 17, 18, 19). Also, the reference teaches that the composition is useful in treating conditions involving infection responsive to an antimicrobially active nitroimidazole drug.

The reference teaches up to 5% of alkylene glycol in example 1 but does not explicitly teaches the composition comprises 15% by weight of more of pentane 1-5 diol

Tsao et al. teaches a disinfection solution comprising C2-C6 alkanol, C3-C8 alkylene glycol, a pharmaceutically acceptable surfactant, optionally a buffer and water (see Abstract). The reference further teaches that the alkylene glycol is selected from

1,2-propylene glycol, 1,2-butylene glycol, 1,5-pentylene glycol etc and the amount range from 10-50% by weight (col. 3, lines 13-19, lines 20-25). The reference also teaches addition of a surfactants and viscosity enhancers such as hydroxy methyl cellulose (col. 7, lines 40-50) to the composition.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Goodman's composition to add more 1, 5 pentane diol to formulate a composition comprising 15% by weight of more of pentane 1-5 diol because of the teachings of Tsao et al. Tsao et al. teaches disinfectant solution primarily for use in contact lenses comprising alkylene glycols such as pentylene glycol in an amount ranging from 10-50% by weight. One having ordinary skill in the art would have been motivated to add such an amount of pentane 1, 5 diol to Goodman's composition in expectation of success in preparing such formulations and using the same in treating infections.

Claim 13, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (U.S. 6,348,203) and further in view of Tsao et al. (5,411,597) as applied to claims 1, 8, 10-13, 20, 22, 23, 24 above and further in view of Noll et al. (U.S. 5,370,876).

Goodman et al. and Tsao et al. teachings discussed as above. Tsao teaches addition of surfactants to the composition comprising alkylene glycols. The reference does not teach explicitly the addition of a detergent in the composition.

Noll et al. teaches a protective skin cream composition comprising 15-40 wt % of an alkali metal fatty acid salt, an effective amount of an antimicrobial compound, 5-20%

of a polyol effective as an emollient (See abstract). The reference further teaches that the water soluble salts of fatty acids are used to provide water repellency.

It would have been obvious to one having ordinary skill in the art to have added detergents such as salts of a fatty acid in the antimicrobial composition of Goodman et al. because of the teachings of Noll. Noll teaches antimicrobial compositions comprising antimicrobial agents, alkali metal fatty acid salt, polyols etc for use as protective creams for healthcare workers. Polyols include pentylene glycol according to the prior art teachings of Tsuzuki et al. (see claim 5, U.S. 6,121,327). One having ordinary skill in the art would have been motivated in adding such salts in an antimicrobial composition comprising an antimicrobial agent and a polyol in expectation of success in preparing such formulations and using the same for therapeutic purposes and also to provide water repellency.

Claims 4, 14, 19, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck et al. (U.S. 5,369, 29) as applied to claims 1, 2, 8-10, 18, 22 and in view of Buseman et al. (U.S. 2002/0192273).

Swanbeck et al. teachings discussed as above.

The reference does not teach the carrier comprises a patch of a woven or non-woven material or combination thereof.

Buseman et al. teaches adhesive patches for treating or preventing bacterial infections for topical applications in a mammal (see p 22-23, claims 100-103).

It would have been obvious to one having ordinary skill in the art to impregnate or add antibacterial compositions comprising a pharmaceutical carrier in patches because

of the prior art teachings. The prior art Buseman et al. teaches adhesive patches in treating bacterial infections in mammals by topical application. Accordingly, one having ordinary skill in the art at the time of the invention would have been motivated to make patches comprising 1, 5 pentane diol and use it in a method of inhibiting the growth of muliple-resistant bacteria because Swanbeck teaches the antimicrobial properties of the compound and Buseman teaches that antimicrobial compositions can be provided via adhesive patches in treating bacterial infections in mammals.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to UMAMAHESWARI RAMACHANDRAN whose telephone number is (571)272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/
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